

Mfr report #
UF/Dist report #
FDA Use Only

A. Patient information

1. Patient ID	2. Age at time of event or Date of birth:	3. Sex <input type="checkbox"/> F <input type="checkbox"/> M <input type="checkbox"/> Unk	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg	5. Height <input type="checkbox"/> in <input type="checkbox"/> cm
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B. ■ Adverse event and/or ■ Product problem

2. If adverse event, patient outcome
(check all that apply)

<input type="checkbox"/> death _____ (mo/day/yr)	<input type="checkbox"/> disability	<input type="checkbox"/> non-serious
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization – initial or prolonged	<input type="checkbox"/> required intervention	
	<input type="checkbox"/> unknown	

3. Describe event or problem (if device, include # of pts)	4. Date of event
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DRAFT: 10/1/98
(Do not use for reporting)

5. Relevant tests/laboratory data, including dates

6. Other relevant history, including preexisting medical conditions (e.g., race, allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

7. Concurrent medical products (including dietary supplements) and therapy dates (exclude treatment of event)

C. Suspect medication(s)

1. Name (include strength and dosage form) a. _____ b. _____	
2. Dose, frequency & route used a. _____ b. _____	3. Therapy dates (if unknown, give duration) from/to (or best estimate) a. _____ b. _____
4. Indication for use a. _____ b. _____	
5. Event abated after use stopped or dose reduced a. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown <input type="checkbox"/> doesn't apply b. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown <input type="checkbox"/> doesn't apply	6. Event reappeared after reintroduction? a. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply b. <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
7. Lot # a. _____ b. _____	8. Expiration date (if known) a. _____ b. _____

D. Initial reporter

1. Name, address (optional: email/fax)	2. Phone number
	3. Date report completed
	4. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no
5. Attachments included? <input type="checkbox"/> yes <input type="checkbox"/> no	6. Initial reporter also sent voluntary report to FDA? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown
7. Occupation/specialty	

E. All manufacturers

1. Contact office – name, address (and principal manufacturing site – devices)	2. Phone number
	3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company rep <input type="checkbox"/> distributor <input type="checkbox"/> importer <input type="checkbox"/> other:
4. Date received by mfr	5. (A)NDA # _____ IND # _____ BLA # _____ pre-1938? <input type="checkbox"/> yes OTC product? <input type="checkbox"/> yes
6. Date report submitted to FDA	7. If IND, protocol #
8. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 7-day <input type="checkbox"/> 30-day <input type="checkbox"/> Initial <input type="checkbox"/> periodic <input type="checkbox"/> follow-up # _____ <input type="checkbox"/> baseline FDA ref #: _____	9. Adverse event term(s)



Submission of a report does not constitute an admission that the product, medical personnel, user facility, importer, or manufacturer caused or contributed to the event.

Page ____ of ____

Mfr. report #	Date of this report
UF/Importer report #	Date of this report

F. Suspect device

1. Manufacturer name, address		
2. Brand name	<input type="checkbox"/> Unk	(For mfr. use only)
3. Type of device	<input type="checkbox"/> Unk	
a. model #		
b. catalog #		
c. serial #		
d. lot #		
e. other #		
4. Expiration date	5. If implanted, give date	6. If explanted, give date
7. Approximate age of device	8. Device available for evaluation? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer Date: _____	9. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____
10. Usage of device <input type="checkbox"/> initial use of device <input type="checkbox"/> reuse <input type="checkbox"/> unknown		

G. Additional event information/codes – devices

1. Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient diagnostic facility <input type="checkbox"/> outpatient treatment facility <input type="checkbox"/> home <input type="checkbox"/> ambulatory surgical facility <input type="checkbox"/> nursing home <input type="checkbox"/> other: _____ specify _____			
2. Event problem codes (refer to coding manual)			
patient code(s)	(Mfr. only) Labeled? <input type="checkbox"/> yes <input type="checkbox"/> no	device code(s)	(Mfr. only) Labeled? <input type="checkbox"/> yes <input type="checkbox"/> no
<input type="text"/>	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="text"/>	<input type="checkbox"/> yes <input type="checkbox"/> no
<input type="text"/>	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="text"/>	<input type="checkbox"/> yes <input type="checkbox"/> no
<input type="text"/>	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="text"/>	<input type="checkbox"/> yes <input type="checkbox"/> no

H. User facility/importer – devices

1. User facility or importer name, address <input type="checkbox"/> user facility <input type="checkbox"/> importer	
2. Contact person	3. Phone number
4. Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	5. Date user facility/importer became aware of event
6. Report sent to manufacturer? <input type="checkbox"/> yes _____ date <input type="checkbox"/> no	7. Report sent to FDA? <input type="checkbox"/> yes _____ date <input type="checkbox"/> no

I. Device manufacturers only

1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction <input type="checkbox"/> other significant adverse event	2. If follow-up, what type <input type="checkbox"/> correction <input type="checkbox"/> additional information <input type="checkbox"/> response to FDA request <input type="checkbox"/> device evaluation	3. Device manufacture date
5. Device evaluated by manufacturer? <input type="checkbox"/> yes <input type="checkbox"/> no, provide code: _____		6. If action reported to FDA under 21 USC 360(f) list correction/removal reporting number
7. Evaluation codes (refer to coding manual) a. method <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> b. results <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> c. conclusions <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>		8. Remedial action initiated? <input type="checkbox"/> yes <input type="checkbox"/> no Type: _____
9. <input type="checkbox"/> Additional manufacturer narrative and/or 10. Corrected data <input type="checkbox"/>		

J. Baseline information – devices

2. FDA product code		3. Device manufactured at other sites? <input type="checkbox"/> yes <input type="checkbox"/> no	
4. Manufacturer's device family name		5. Related device identification: previous report number	
6. Device life a. Shelf life _____ months <input type="checkbox"/> N/A Is shelf life labeled? <input type="checkbox"/> yes <input type="checkbox"/> no b. Expected life _____ months <input type="checkbox"/> N/A <input type="checkbox"/> Not established/indefinite			
7. Date device first marketed		8. Date device ceased being marketed (if applicable)	
9. Basis for marketing (check one) <input type="checkbox"/> a. 510 (k) number _____ <input type="checkbox"/> b. PMA number _____ <input type="checkbox"/> c. Preamendment <input type="checkbox"/> d. Transitional <input type="checkbox"/> e. 510 (k) Exempt			
10. Device reporting site registration number and street address			